

Application No.: 09/449,851

Docket No.: CIMA 3.0-035

IN THE CLAIMS

1. (currently amended) A taste masked formulation which rapidly releases a drug in the stomach of a patient comprising:

a drug-containing core;

a taste masking layer having a thickness of between about 5 and about 75 microns composed of a material which is generally insoluble in saliva at a neutral to basic pH and completely soluble in saliva at a pH of less than about 6.5; and

a spacing layer having a thickness of between about 5 and about 75 microns surrounding said core and substantially completely sequestering said core from said taste masking layer and being capable of rapidly exposing said core when exposed in the stomach of a patient; said taste masking layer preventing exposure of said spacing layer in the mouth of a patient for a period of at least about 20 seconds after being placed into the mouth and being capable of rapidly exposing said spacing layer when in the stomach of a patient; wherein the taste-masked formulation disintegrates in the mouth of a patient in less than 90 seconds to form a suspension of particles; wherein the coated drug-containing core generally has a diameter of no larger than 1,500 microns.

2. (canceled)

3. (canceled)

4. (canceled)

2 5. (original) The formulation of claim 1 wherein said drug is a pharmaceutically active material, a vitamin, a mineral, a nutritional supplement and mixtures thereof.

3 6. (original) The formulation of claim 1 wherein said spacing layer increases the weight of the core by between about 5 and about 100 percent by weight.

4 7. (original) The formulation of claim 6 wherein said spacing layer increases the weight of the core by between about 20 and about 50 percent by weight.

8. (canceled)

5 9. (currently amended) The formulation of claim 8-1 wherein said spacing layer has a thickness of between about 5 and about 30 microns.

6 10. (original) The formulation of claim 1 wherein said taste masking layer increases the weight of the core by between about 5 and about 100 percent by weight.

7 11. (original) The formulation of claim 10 wherein said taste masking layer increases the weight of the core by between about 20 and about 70 percent by weight.

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12. (canceled)

8 13. (currently amended) The formulation of claim ~~12-1~~ wherein said taste masking layer has a thickness of between about 5 and about 30 microns.

9 14. (currently amended) A dosage form intended for direct oral administration, comprising:

an effective amount of at least one drug, said drug present in the cores of coated particles, said ~~cores~~ particles including a taste masking layer having a thickness of between about 5 and about 75 microns composed of a material which is generally insoluble in saliva at a neutral to basic pH and completely soluble in saliva at a pH of less than about 6.5; and

a spacing layer having a thickness of between about 5 and about 75 microns surrounding said core and substantially completely sequestering said core from said taste masking layer and being capable of rapidly exposing said core when exposed in the stomach of a patient; said taste masking layer preventing exposure of said spacing layer in the mouth of a patient for a period of at least about 20 seconds after being placed into the mouth and being capable of rapidly exposing said spacing layer when in the stomach of a patient; and

at least one pharmaceutically acceptable excipient provided in an amount of between greater than zero and less than 100%, based on the weight of the finished dosage form; wherein the taste-masked formulation disintegrates in the mouth of a patient in less than 90 seconds to form a suspension of particles; wherein the coated drug-containing core generally has a diameter of no larger than 1,500 microns.

10 15. (original) The dosage form of claim 14 wherein said coated particles are present in an amount of between greater than zero and about 95% by weight based on the weight of the finished dosage forms.

11 16. (original) The dosage form of claim 15 wherein said coated particles are present in an amount of between greater than zero and about 75% by weight based on the weight of the finished dosage forms.

12 17. (original) The dosage form of claim 14 further comprising a disintegrant wherein the amount of said disintegrant and said excipient are between greater than zero and about 95% by weight based on the weight of the finished dosage forms.

13 18. (original) The dosage form of claim 17 wherein said disintegrant and said excipient are present in an amount of between greater than zero and about 75% by weight based on the weight of the finished dosage forms.

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19. (canceled)
20. (canceled)
21. (canceled)
- 14 22. (previously presented) The taste masked formulation of claim 1, wherein the coated drug-containing core has a diameter of no larger than 1200 microns.
- 15 23. (previously presented) The taste masked formulation of claim 22, wherein the coated drug-containing core has a diameter of no larger than 850 microns. 14
- 16 24. (previously presented) The dosage form of claim 14, wherein the coated drug-containing core has a diameter of no larger than 1200 microns.
- 17 25. (previously presented) The dosage form of claim 24, wherein the coated drug-containing core has a diameter of no larger than 850 microns. 16